

Special 510(k): Device Modification
Infinity Gamma/GammaXL and Vista with VF5 software

510(k) SUMMARY
as required per 807.92(c)

Submitters Name, Address:

Draeger Medical Systems, Inc.
16 Electronics Avenue
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879

Contact person for this submission: Penelope H. Greco
Regulatory Submissions Manager

Date submission was prepared: September 24, 2004

Trade Name, Common Name and Classification Name:

Trade Name: INFINITY Gamma/GammaXL and Vista with VF5 modifications

Common Name, Classification Name, Class and Regulation Number:

Common Name	Product Code	Class	Regulation Number
Monitor, Physiological, Patient (with Arrhythmia Detection or Alarms)	MHX	II	870.1025
Arrhythmia Detector & Alarm	74DSI	II	870.1025
System, Network and Communication, Physiological Monitors	MSX	II	870.2300

Legally Marketed Device:

INFINITY GammaXL & SC 6802XL with Scio	K033600, K040188
Infinity Gamma	K041087

Description of Device Modifications:

Software version VF5 is the latest release of the INFINITY Gamma/GammaXL and the Infinity Vista monitor (a variant of the Infinity GammaXL with fewer options). It supports a new serial connection to the Scio gas module, as well as other minor software modifications. Testing in accordance with internal design control procedures has verified that the INFINITY Gamma/GammaXL and Vista with VF5 modifications are as safe and effective as submitted in 510(k) K040188, K041087 and K033600.

Intended Use:

The intended use of this device is to monitor heart rate, respiration rate, invasive pressure, non-invasive pressure*, arrhythmia, temperature, arterial oxygen saturation and pulse rate, central apnea, end-tidal carbon dioxide*, and ST Segment Analysis. This device will produce visual and audible alarms if any of these parameters vary beyond preset limits and produce timed or alarm recordings. This device will connect to R50 recorders, either directly or via the INFINITY network.

* not available with the Infinity Vista monitor

COMPANY CONFIDENTIAL

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Assessment of non-clinical performance data for equivalence: Verification and validation testing performed indicates that the modifications implemented with software version VF5 are as safe and effective as previous versions and have not altered the fundamental technology of the device(s).

Assessment of clinical performance data for equivalence: Not applicable

Biocompatibility: Not applicable

Sterilization: Not applicable

Standards: IEC 60601-1

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 6 - 2004

Draeger Medical Systems Inc.
c/o Ms. Penelope H. Greco
Manager Regulatory Submissions
16 Electronics Avenue
Danvers, MD 01923

Re: K042656

Trade Name: INFINITY Gamma/GammaXL and Vista

Regulation Number: 21 CFR 870.1025

Regulation Name: Arrhythmia Detector and Alarm (including ST-segment measurement
and alarm)

Regulatory Class: II (two)

Product Code: MHX

Dated: September 24, 2004

Received: September 28, 2004

Dear Ms. Greco :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

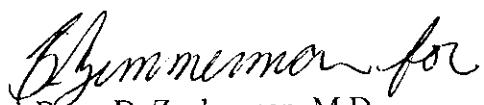
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
<http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: INFINITY Gamma/GammaXL and Vista

Indications for Use:

This devices are capable of monitoring:

- Heart Rate
- Respiration Rate
- Invasive Pressure
- Non-Invasive Pressure
- Arrhythmia
- Temperature
- Arterial oxygen saturation
- Pulse rate
- central apnea
- end-tidal CO₂*
- ST Segment Analysis

This device will produce visual and audible alarms if any of these parameters vary beyond preset limits and produce timed or alarm recordings. This device will connect to R50 recorders, either directly or via the INFINITY network.

When a GammaXL is connected to a SCIO module sampled breathing gases from adults and pediatrics can be displayed. The gas module continuously measures the content of CO₂, N₂O, O₂ and one of the anesthetic agents, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane in any mixture and communicates real time and derived gas information to the GammaXL.

The device is intended to be used in an environment where patient care is provided by Healthcare Professionals, i.e. physicians, nurses, and technicians, trained on the use of the device, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

The devices are intended for use in the Adult, Pediatric and Neonatal populations, *with the exception of Arrhythmia and ST Segment Analysis which are not intended for the neonatal population.*

* not available with Infinity Vista

MRI Compatibility Statement:

The devices are not compatible for use in an MRI magnetic field.

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B. Zimmerman
(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K042656